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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Michael A. Brownlee

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AMSTER, ROTHSTEIN & EBENSTEIN LLP
90 PARK AVENUE
NEW YORK, NY 10016

EXAMINER

CORDERO GARCIA, MARCELA M

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/582,116	Applicant(s) BROWNLEE, MICHAEL A.	
	Examiner MARCELA M. CORDERO GARCIA	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 72-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 72-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/18/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to the reply received on 11/18/2010.

Any rejection from the previous office action, which is not restated here, is withdrawn.

Election/Restrictions

2. Applicant's election without traverse of Group I, drawn to a method of inhibiting hyperglycemia-induced or free fatty acid-induced reactive oxygen formation comprising treating the cell with a pharmaceutically acceptable composition comprising GLP-1(9-36) in the reply filed on July 6, 2009 was previously acknowledged.

Applicant's election without traverse of the species corresponding to SEQ ID NO:1 and inhibition of hyperglycemia-induced reactive oxygen formation in the reply filed on July 6, 2009 was also previously acknowledged.

Status of the claims

3. Claims 1, 3, 4, 7, 18, 19, 23, 24, 29-31, 51-54, 62 and 67-70 were previously pending in the application. Claims 1, 3, 4, 7, 18, 19, 23, 24, 29-31, 51-54, 62 and 67-70 have been cancelled. New claims 72-78 are now pending and are presented for examination in the merits. Applicants state that no new matter has been introduced and cite the application as a whole. See, e.g., page 10.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 51-54 and 62 were previously rejected under 35 U.S.C. 102(b) as being anticipated by Coolidge et al. (US 6,429,197).

This rejection is withdrawn in view of Applicant's arguments and amendments to the claims.

6. Claims 72-78 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson et al. (US 5,574,008, cited in the IDS dated August 13, 2009).

Johnson et al. (US 5,574,008) teach treating diabetes or hyperglycemia by administration of GLP- 1 (9-36) of, e.g., instant SEQ ID NO: 1 (see claims 1-8 of Johnson et al.) to a mammal in need thereof such as a human being having diabetes (e.g., cols. 3 and 8, claims). Johnson et al. teach that the GLP-1 fragments have the ability to lower elevated levels of blood glucose in a mammal without stimulating insulin secretion (e.g., col.3). Johnson et al. teach that the GLP-1 fragments may be administered intramuscularly and subcutaneously. Parenteral daily dosage preferably a single, daily dose are in the range from about 1 pg/kg to about 1,000 ug/kg of body weight, although lower or higher dosages may be administered. The required dosage will depend upon the severity of the condition of the patient and upon such criteria as the patient's height, weight, sex, age and medical history (e.g., col. 7). Sustained release formulas may be achieved by the use of polymers to complex or absorb a compound. The controlled delivery may be exercised by selecting appropriate macromolecules. Johnson et al. do not expressly teach the limitation drawn to an amount "sufficient to inhibit the development of vascular disease in the mammal".

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However, the instant application does not appear to provide specific guidance regarding these amounts sufficient to inhibit the development of vascular disease in the mammal.

The disclosure does, however, indicate that such amounts may be found by those skilled in the art (e.g., page 7) using standard dose-response protocols, and provides Example 3 which sets forth dosages (10ug/100uL) in diabetic mice to reduce diabetes-induced reactive oxygen formation and physiological systems affected by reactive oxygen (e.g. pages 14-15 of the instant disclosure). This dosage is within those taught by Johnson et al. (e.g., col. 7). Although Johnson et al. do not expressly teach the preamble "a method for inhibiting the development of vascular disease in a mammal having diabetes", it is noted that the determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case; there is no litmus test defining when a preamble limits the scope of a claim (see MPEP 2111.02). In the instant case Johnson et al. do teach all the active steps and population instantly claimed and therefore inherently reads upon the claimed method. The limitations "inhibiting the development of vascular disease", and "sufficient to inhibit the development of vascular disease" do not require that the diabetic mammal suffer from any vascular disease, and therefore reads upon a diabetic patient having no symptoms of vascular disease (such as coronary disease, myocardial infarction, atherosclerotic peripheral vascular disease, cerebrovascular disease, stroke, renal disease or cardiomyopathy) such as disclosed and claimed in the Johnson et al. patent. Furthermore, "[t]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the

discoverer.” Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. (See MPEP 2112).

Therefore the reference is deemed to anticipate the claims above.

Applicant's arguments

7. Applicants argue that Johnson does not teach inhibiting the development of vascular disease in a mammal having diabetes by treating the mammal with a pharmaceutically acceptable composition comprising GLP-1 (9-36) sufficient to inhibit the development of vascular disease in the mammal. Accordingly, Johnson does not anticipate the claimed invention, and reconsideration and withdrawal of this rejection is respectfully requested.

Response to arguments

8. Applicant's arguments have been carefully considered but not deemed persuasive for the reasons set forth above and for the following reasons:

Johnson et al. do not expressly teach the limitation drawn to an amount "sufficient to inhibit the development of vascular disease in the mammal". However, the instant application does not appear to provide specific guidance regarding these amounts sufficient to inhibit the development of vascular disease in the mammal. The disclosure does, however, indicate that such amounts may be found by those skilled in the art (e.g., page 7) using standard dose-response protocols, and provides Example 3 which sets forth dosages (10ug/100uL) in diabetic mice to reduce diabetes-induced reactive oxygen formation and physiological systems affected by reactive oxygen (e.g.

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pages 14-15 of the instant disclosure). This dosage is within those taught by Johnson et al. (e.g., col. 7). Although Johnson et al. do not expressly teach the preamble "a method for inhibiting the development of vascular disease in a mammal having diabetes", it is noted that the determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case; there is no litmus test defining when a preamble limits the scope of a claim (see MPEP 2111.02). In the instant case Johnson et al. do teach all the active steps and population instantly claimed and therefore inherently reads upon the claimed method. The limitations "inhibiting the development of vascular disease", and "sufficient to inhibit the development of vascular disease" do not require that the diabetic mammal suffer from any vascular disease, and therefore reads upon a diabetic patient having no symptoms of vascular disease (such as coronary disease, myocardial infarction, atherosclerotic peripheral vascular disease, cerebrovascular disease, stroke, renal disease or cardiomyopathy) such as disclosed and claimed in the Johnson et al. patent. Furthermore, "[t]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. (See MPEP 2112).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1, 24 were previously rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 5,574,008, cited in the IDS dated August 13, 2009) in view of Knudsen et al (US 6,268,343).

This rejection is withdrawn in view of Applicant's amendments to the claims.

11. Claims 1, 3-4, 7, 18, 19, 23, 29-30, 51-53 and 62 were previously rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 5,574,008) in view of Vincent et al. (Ann. N. Y. Acad. Sci. 2002).

This rejection is withdrawn in view of Applicant's amendments to the claims.

12. Claims 72-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holst et al. (WO 02/085406, cited in the IDS dated 6/26/2007).

Holst et al. disclose a method of inhibiting the development of vascular disease, the method comprising treating the mammal having insulin-resistance a pharmaceutically acceptable composition comprising GLP-1 (9-36) sufficient to inhibit the development of vascular disease in the mammal (e.g., pages 2-5). Holst et al. disclose treating insulin-resistance patients, e.g., diabetic patients (Examples, pages 29-39). The amount of the GLP-1 molecule is between 0.1-1000 pmol/kg body weight/minute. In some embodiments the dosage is 0.1-10 pmoles/kg body weight/minute (when administered by infusion) (page 27). See also, e.g., claims, which teach treating a subject suffering from an insulin-associated condition such as

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atherosclerotic cardiovascular disease (ASCD), congestive heart failure (e.g., page 4), or cardiac metabolic myopathy (e.g., claims).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer GLP-1 (9-36) to a diabetic patient, as taught in the Examples of Holst et al. and in the claims. One of ordinary skill in the art at the time the invention was made would have been motivated to do so in order to inhibit insulin-resistance associated conditions such as atherosclerotic cardiovascular disease (ASCD), congestive heart failure (e.g., page 4) in the diabetic patient. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success giving that the dosages taught by Holst et al. were encompassed by the therapeutic dosages disclosed by the instant disclosure. Since Holst et al. does teach all the active steps instantly claimed, including active dosages, it does necessarily follow that other cardiovascular disease such as stroke, renal disease, etc. would be prevented by administration of GLP-1 (9-36) to a diabetic patient. “[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer.” Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. (See MPEP 2112).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

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ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

13. No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCELA M. CORDERO GARCIA whose telephone number is (571)272-2939. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marcela M Cordero Garcia/
Primary Examiner, Art Unit 1654

MMCG 02/2011